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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,120	07/10/2001	Wei-Sing Chu	2313-118	8943

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/901,120	CHU, WEI-SING	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *84-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *84-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 23, 2005 has been entered.

Response to Amendment

2. Applicant's amendment of claim 84 is acknowledged and has been entered.

3. Applicant's addition of claims 94-100 is acknowledged and has been entered.

4. Claims 84-100 are pending.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 84, 87, 89,90, 96, 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger [US 5,089,288] in view of Buckin et al [US 5,983,723].

With respect to claim 84, Buckin et al teach a treatment vessel comprising a working receptacle (column 3, liens 15-25), a tissue sample that has been fixed with isopropyl alcohol

(abstract), and an ultrasound generator provided on the vessel controlled by a electric generator having a frequency in the ultrasound range (column 3, lines 29-35). Berger et al fail to teach transducers that are disposed movably on the reaction chamber.

Buckin et al, however, teach transducers that are disposed movable on the apparatus, so that they may be shifted from a resting position into a working position (column 2, lines 4-10) and further teach that this facilitates cleaning operations and makes sterilization or exchange of a chamber possible (column 2, lines 38-42).

Therefore, it would have been obvious to one of ordinary skill in the art to make the transducers disposed on the working receptacle of Berger et al moveable, as suggested by Buckin et al, in order to facilitate cleaning operations and make sterilization or exchange of a chamber possible.

7. With respect to claim 87, Berger et al teach heating means (column 3, lines 16-20).

8. With respect to claim 89, Berger et al teach a pump system and/or valve system making it possible to move individual treating media from tanks into the inner chamber of the working receptacle and to return media from the inner chamber back to the tanks (column 4, lines 13-20).

9. With respect to claim 90, Berger et al teach tissue samples (column 3, lines 60-63).

10. With respect to claim 96, Berger et al teach 100% isopropyl alcohol (column 4, lines 1-12).

11. With respect to claim 98, Berger et al teach paraffin (column 4, lines 1-5).

12. Claim 94 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berger [US 5,089,288] in view of Buckin et al [US 5,983,723] and further in view of Hunt et al [US 4,495,817].

With respect to claim 94, Buckin et al teach a treatment vessel comprising a working receptacle (column 3, liens 15-25), a tissue sample that has been fixed with isopropyl alcohol (abstract), and an ultrasound generator provided on the vessel controlled by a electric generator having a frequency in the ultrasound range (column 3, lines 29-35). Berger et al fail to teach that the transducer is ceramic, and Buckin et al fail to correct this deficiency.

Hunt et al, however, teach that ceramic piezoelectric discs are readily available and efficient and can be used as transducer elements (column 5, lines 64-67). Hunt et al further teach that the piezoelectric ceramic tranducers are capable of frequencies of 0.2 to 5 MHz (column 4, lines 39-45)

Therefore, it would have been obvious to use ceramic piezoelectric discs as the transducers in the invention of Berger et al and Buckin et al, as suggested by Hunt et al, since ceramic piezoelectric discs are readily available and efficient.

It should be noted that the limitation that ultrasound is applied at 0.01 to 5 W/cm^2 is considered an intended use, and therefore has not been given any patentable weight in the claim, which is drawn to a product.

13. Claims 95, 97, are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger [US 5,089,288] in view of Buckin et al [US 5,983,723], and further in view of Chu [US 5,958,341].

With respect to claims 95, 97, Berger et al. teach the invention substantially as discussed above. Berger et al further teach that the tissues can be fixed using solutions such as alcohol and paraffin (column 4, lines 1-5). Berger et al fail to teach other fixing solutions such as formalin or xylene.

Chu, however, teach preparing a tissue sample with 10% formalin and later treated with xylene in order to fix the tissue (column 18, lines 5-15) for PCR analysis (column 20, example 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to immerse the tissue sample in the solutions as taught by Chu in the Berger et al invention, since Berger et al teach that the samples may be fixed, and Chu teach that these solutions are used in preparing tissue samples for PCR, particularly in fixing. Therefore, because these two were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute formalin and xylene for paraffin and alchol.

14. Claims 99 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berger [US 5,089,288] in view of Buckin et al [US 5,983,723] and Chu [US 5,958,341] and further in view of Weier et al [US 5,427,932].

With respect to claim 99, Berger et al. teach the invention substantially as discussed above. Berger et al further teach that the tissues can be fixed using solutions such as alcohol and paraffin (column 4, lines 1-5). Chu further teaches preparing a tissue sample with 10% formalin embedded in paraffin and later treated with xylene and ethanol in order to fix the tissue (column 18, lines 5-15) for PCR analysis (column 20, example 4). Chu also teaches labeling the tissue with biotinylated or digoxigen labeled probes during hybridization (column 18, lines 39-60). Neither Chu nor Berger et al teach the use of FITC-labeled probes.
Weier et al, however, teach the use of both biotinylated DNA probes (column 24, lines 40-45) and avidin-FITC DNA probes (column 25, lines 15-20) during processing of tissue sections

during hybridization. Since Weier et al show that avidin-FITC probes is an equivalent structure known in the art.

Therefore, because these two probes were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute avidin-FITC probes for biotinylated probes in the invention of Berger et al, Chu, and Buckin et al.

15. Claims 84-89, 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al [US 5,639,423] in view of Buckin et al [US 5,983,723].

With respect to claim 84, Northrup et al teach ultrasonic Lamb-wave devices (abstract) comprising a reactor equipped with a Lamb-wave transducer (ultrasound generator) (column 7, lines 29-35) and Lamb-wave sensor (ultrasound sensor) in a solution in a chamber (reaction chamber) (column 7, lines 29-35), where the transducer is located on a thin film wall of the chamber (claims 1, 3). Northrup et al further teach sensors for measuring density and viscosity (column 11, lines 40-48). Northrup et al also teach a power source/control system (fig.1, column 6, lines 53-63) for controlling the reaction, either by inductive coupling, capacitive coupling, or by electromagnetic coupling. Detection signals may be processed and stored by integrated microelectronic devices so that result interpretation and control mechanisms which may utilize feedback can be integrally contained (central processing unit) (column 4, lines 40-45). Northrup et al further teach that the reactor may be used to process fixed cells or tissues for PCR and subsequent techniques (column 5, lines 42-61). Northrup et al fail to teach transducers that are disposed movably on the reaction chamber.

Buckin et al, however, teach transducers that are disposed movable on the apparatus, so that they may be shifted from a resting position into a working position (column 2, lines 4-10) and further teach that this facilitates cleaning operations and makes sterilization or exchange of a chamber possible (column 2, lines 38-42).

Therefore, it would have been obvious to one of ordinary skill in the art to make the transducers disposed on the reaction chamber of Northrup et al moveable, as suggested by Buckin et al, in order to facilitate cleaning operations and make sterilization or exchange of a chamber possible.

With respect to claim 85, Northrup et al teach multiple transducers (column 7, lines 50-55).

With respect to claim 86, Northrup et al teach Lamb-wave sensors (column 11, lines 39-42).

With respect to claim 87, Northrup et al teach a heater (column 7, lines 28-35).

With respect to claim 88, Northrup et al teach multiple pumps (column 7, lines 50-55).

With respect to claim 89, Northrup et al teach integrated instruments for small-volume reagent delivery (column 5, lines 17-20).

With respect to claim 91, Nothrup et al teach a silicone window through which a hypodermic needle may insert a sample (column 6, lines 52-60). The hypodermic needle would therefore also be capable of sampling reaction fluid.

With respect to claims 92, 93, although Northrup et al do not specifically teach that the ultrasound transducer is disposed within about 2 inches or about 1 inch of the sample, Nothrup et al do teach that the whole instrument may fit on a wafer as small as 1 cm x 1 cm x 0.5 cm

(column 5, lines 40-48). Therefore, the transducers would be default be within 1 inch of the sample.

16. Claims 90, 95, 97, 98, 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al. [US 5,639,423] in view of Buckin et al [US 5,983,723], and further in view of Chu [US 5,958,341].

With respect to claims 90, 95, 97, 98, Northrup et al. teach the invention substantially as claimed. Northrup et al. teach that the device can be used to process fixed cells as well as tissue samples for PCR and subsequent techniques (column 5, lines 40-60). However, Northrup et al. do not teach that the sample is immersed in a solution of formalin, alcohol, xylene or parafin.

Chu, however, teach preparing a tissue sample with 10% formalin embedded in paraffin and later treated with xylene and ethanol in order to fix the tissue (column 18, lines 5-15) for PCR analysis (column 20, example 4).

Therfore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to immerse the tissue sample in the solutions as taught by Chu in the Northrup et al invention, since Northrup et al teach that the samples may be fixed, and Chu teach that these solutions are used in preparing tissue samples for PCR, particularly in fixing.

With respect to claim 100, Chu et al teach that the staining of the samples may include antibodies (column 10, lines 50-60).

17. Claim 94 is rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al [US 5,639,423] in view of Buckin et al [US 5,983,723] and further in view of Hunt et al [US 4,495,817].

With respect to claim 94, Northrup et al teach ultrasonic Lamb-wave devices (abstract) comprising a reactor equipped with a Lamb-wave transducer (ultrasound generator) (column 7, lines 29-35) and Lamb-wave sensor (ultrasound sensor) in a solution in a chamber (reaction chamber) (column 7, lines 29-35), where the transducer is located on a thin film wall of the chamber (claims 1, 3). Northrup et al further teach transducers with frequencies of 1 to 200 MHz (column 11, lines 1-10) Northrup et al fail to teach that the transducer is ceramic, and Buckin et al fail to correct this deficiency.

Hunt et al, however, teach that ceramic piezoelectric discs are readily available and efficient and can be used as transducer elements (column 5, lines 64-67).

Therefore, it would have been obvious to use ceramic piezoelectric discs as the transducers in the invention of Northrup et al and Buckin et al, as suggested by Hunt et al, since ceramic piezoelectric discs are readily available and efficient.

It should be noted that the limitation that ultrasound is applied at 0.01 to 5 W/cm^2 is considered an intended use, and therefore has not been given any patentable weight in the claim, which is drawn to a product.

18. Claims 99 is rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al. [US 5,639,423] in view of Buckin et al [US 5,983,723] and Chu [US 5,958,341] and further in view of Weier et al [US 5,427,932].

With respect to claims 99, Northrup et al. teach the invention substantially as claimed. Northrup et al. teach that the device can be used to process fixed cells as well as tissue samples for PCR and subsequent techniques (column 5, lines 40-60). Chu further teaches preparing a

tissue sample with 10% formalin embedded in paraffin and later treated with xylene and ethanol in order to fix the tissue (column 18, lines 5-15) for PCR analysis (column 20, example 4). Chu also teaches labeling the tissue with biotinylated or digoxigen labeled probes during hybridization (column 18, lines 39-60). Neither Chu nor Northrup et al teach the use of FITC-labeled probes.

Weier et al, however, teach the use of both biotinylated DNA probes (column 24, lines 40-45) and avidin-FITC DNA probes (column 25, lines 15-20) during processing of tissue sections during hybridization. Since Weier et al show that avidin-FITC probes is an equivalent structure known in the art. Therefore, because these two probes were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute avidin-FITC probes for biotinylated probes in the invention of Northrup et al, Chu, and Buckin et al.

Response to Arguments

19. Applicant's arguments with respect to claims 84-94 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

20. No claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
3/18/06